

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

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JACQUELINE M. DUNCAN, \*

Petitioner, \*

v. \*

SECRETARY OF HEALTH \*

AND HUMAN SERVICES, \*

Respondent. \*

\* \* \* \* \*

No. 16-1367V

Special Master Christian J. Moran

Filed: October 19, 2020

Dismissal, order to show  
cause, PANDAS

Braden Blumenstiel, Blumenstiel Falvo, LLC, Dublin, OH, for petitioner;  
Mollie Gorney, United States Dep't of Justice, Washington, DC, for respondent.

### **DECISION DENYING COMPENSATION**<sup>1</sup>

Jacqueline Duncan alleged that an HPV vaccination significantly aggravated her PANDAS in a petition filed on October 19, 2016. After four years, Ms. Duncan has not presented minimally competent evidence to substantiate her claim. Therefore, her claim is dismissed.

#### **I. Procedural History**

Represented by Attorney James Blumenstiel, Ms. Duncan submitted her petition in October 2016. Relevant allegations from the petition include that she

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<sup>1</sup> Because this published decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). This posting means the decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

was diagnosed as suffering from pediatric autoimmune neuropsychiatric disorder association strep (“PANDAS”). She received one dose of the human papillomavirus (“HPV”) vaccine in 2011 to which she had no adverse reaction. In October 2013, she received another dose and felt much worse. Pet., filed Oct. 16, 2016, ¶ 7-9. Ms. Duncan alleges that the October 28, 2013 HPV vaccination significantly aggravated her underlying PANDAS. *Id.* ¶ 10. She filed medical records and, then, a statement of completion on December 27, 2016.

The Secretary evaluated the evidence Ms. Duncan had submitted and concluded that Ms. Duncan was not entitled to compensation. Resp’t’s Rep., filed pursuant to Vaccine Rule 4, on Mar. 8, 2017. Specifically, the Secretary argued, among other points, that Ms. Duncan failed to provide a reliable medical theory connecting the October 2013 vaccination to any problems after that vaccination. Resp’t’s Rep. at 8. The Secretary also noted that no medical records created around October or November 2013 document that Ms. Duncan became much worse after the October 2013 vaccination. *Id.*<sup>2</sup>

In the effort to develop her claim, Ms. Duncan submitted a letter from Michael Joseph, a doctor who treated her. Exhibit 31. However, Dr. Joseph’s letter did not, by itself, establish that an HPV vaccination aggravated Ms. Duncan’s PANDAS. To further assist Ms. Duncan and her attorney, the undersigned proposed a set of instructions to guide any expert in the presentation of reports. Orders, issued July 21, 2017 (draft instructions) and Aug. 8, 2017 (final instructions). Approximately five months elapsed during which Ms. Duncan did not submit an expert report.

Attorney Braden Blumenstiel, the son of Attorney James Blumenstiel, became counsel of record on December 28, 2017. (This decision refers to Mr. Braden Blumenstiel as “Mr. Blumenstiel.”) Mr. Blumenstiel has represented Ms. Duncan for the ensuing three years. Between December 2017 and August 2018, Ms. Duncan filed a series of status reports. However, over those approximately eight months, she did not file an expert report.

A status conference was held on September 17, 2018. Mr. Blumenstiel was again advised to obtain an expert report. Mr. Blumenstiel suggested that he might retain a biomedical engineer. The undersigned indicated that opinions from people

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<sup>2</sup> The Secretary also challenged Ms. Duncan’s receipt of vaccination. Ms. Duncan developed evidence to support the vaccination, including exhibit 38. After the submission of this evidence, the Secretary was satisfied with Ms. Duncan’s proof regarding vaccination. *See* order, issued July 21, 2017.

without medical degrees are uncommon in the Vaccine Program. Nevertheless, Mr. Blumenstiel wanted to proceed. In reliance upon Mr. Blumenstiel's representations, Ms. Duncan was ordered to file an expert report by November 26, 2018. Order, issued Sept. 24, 2018.

One day late, Ms. Duncan submitted a report from James Lyons-Weiler. Exhibit 39. Mr. Lyons-Weiler is not a medical doctor. Instead, he has a Ph.D. in ecology. Mr. Lyons-Weiler presented a largely unpersuasive report that (1) almost entirely relied on affidavits, rather than medical records, to summarize the pertinent medical facts, (2) presented a medical theory in only two paragraphs with a list of references, and (3) did not address the expected course of PANDAS absent the vaccination.

After another status conference, Ms. Duncan was again ordered to obtain an expert report. The deadline was set for April 23, 2019. Order, issued Feb. 22, 2019. Mr. Blumenstiel filed a series of motions for enlargement of time, which were all granted.

On November 27, 2019 (approximately nine months after the February 22, 2019 order), Ms. Duncan filed another report from Dr. Joseph. Exhibit 58. This report, too, was discussed in another status conference, which was held on December 5, 2019.

An order to show cause was issued on February 24, 2020. Ms. Duncan was alerted that if she failed to present "a credible, competent, and complete opinion to support her claim that the HPV vaccination significantly aggravated her PANDAS," then her claim would be dismissed. The deadline was set as April 24, 2020.

After the April 24, 2020 deadline passed, chambers staff informally communicated with Mr. Blumenstiel about the missed deadline. On May 18, 2020, Ms. Duncan moved for a 60-day extension of time to respond to the order to show cause, to file any remaining evidence, and to file a motion for ruling on the record. Mr. Blumenstiel explained that the April 24, 2020 due date was not calendared resulting in his untimely submission. Counsel also noted that the expected easing of the state-mandated lockdown due to the coronavirus would making obtaining additional evidence easier. In a filing submitted on the next day, Ms. Duncan indicated that the Secretary did not consent to petitioner's motion but deferred to the undersigned. Ms. Duncan was afforded additional time. Order, issued May 20, 2020.

Ms. Duncan argued that her case should not be dismissed in a nine-page response. Pet'r's Resp. to Order to Show Cause, filed July 20, 2020. With her submission, Ms. Duncan also presented eight exhibits.<sup>3</sup> Eleven days later, Mr. Blumenstiel stated that he was scheduled to meet Dr. Joseph and would file an updated report from him. Pet'r's Status Rep., filed July 31, 2020.

The Secretary maintained that Ms. Duncan's case should be dismissed. In the Secretary's view, Ms. Duncan had many opportunities to present evidence supporting her case. However, Ms. Duncan did not present evidence that carries her burden of proof. Resp't's Resp. to Order to Show Cause, filed Aug. 24, 2020.

To avoid any misunderstandings, the undersigned provided that Ms. Duncan could file a reply to the Secretary's argument. The undersigned also allowed Ms. Duncan to file any supplemental material from Dr. Joseph, as Mr. Blumenstiel had suggested in his July 31, 2020 status report. The deadline for those submissions was September 8, 2020. Order, issued Aug. 31, 2020.

Ms. Duncan has not replied, making the matter ready for adjudication.

## **II. Method of Adjudication**

Preliminarily, Ms. Duncan argues that "the proper course is for the respondent to move for summary judgment." Pet'r's Resp. at 3; accord id. at 4 n.1, id. at 8. However, a motion for summary judgment is not required.

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (reflected in Vaccine Rule 8(c) & (d)). In Kreizenbeck v. Sec'y of Health & Human Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018), the petitioners argued that because they objected to a ruling on the record, the appropriate procedure was a motion for summary judgment. However, the Federal Circuit disagreed with this contention. "[Vaccine] Rule 8(d) contemplates that special masters can decide cases on written submissions *other* than motions for summary judgment." 945 F.3d at 1366.

While the Federal Circuit recognized that special masters may resolve a case based on written submissions, the Federal Circuit recognized that special masters "must 'afford[] each party a full and fair opportunity to present its case.'" Id. at 1366, quoting Vaccine Rule 3(b)(2). Here, Ms. Duncan has been allowed "a full

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<sup>3</sup> Ms. Duncan actually submitted a ninth exhibit as well. However, that exhibit was struck and Ms. Duncan was ordered to refile it. Order, issued July 22, 2020. Ms. Duncan has not refiled the struck exhibit.

and fair opportunity” to present evidence supporting her claim. As detailed in the procedural history, the undersigned issued instructions to guide the development of expert reports in August 2017. Over the ensuing three years, Ms. Duncan has been counseled about the deficiencies in the reports from her experts.

The deficiencies in the reports from her experts, which are discussed below, is the basis for the dismissal. Although Ms. Duncan suggests that a dismissal with prejudice is a “sanction” reserved for extreme cases, Pet’r’s Resp. at 2, the term “sanction” fits this situation poorly, if at all. Ms. Duncan is not being punished for misconduct. While Ms. Duncan’s compliance with deadlines and other orders falls short of ideal, the dismissal is not a consequence of missing a deadline. Her case is being dismissed because her evidence is not adequate. In the sense of not presenting persuasive evidence, Ms. Duncan is like other petitioners whose cases fall short of the evidentiary standard. Therefore, to the extent that Ms. Duncan is requesting that her case be evaluated based upon the evidence that she has presented, the undersigned agrees.

### **III. Standards for Adjudication**

As confirmed in W.C. v. Sec’y of Health & Human Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013), the elements of an off-Table significant aggravation case were stated in Loving v. Sec’y of Dep’t of Health & Human Servs., 86 Fed. Cl. 135 (2009). There, the Court of Federal Claims blended the test from Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1279 (Fed. Cir. 2005), which defines off-Table causation cases, with a test from Whitecotton v. Sec’y of Health & Human Servs., 81 F.3d 1099, 1107 (Fed. Cir. 1996), which concerns on-Table significant aggravation cases. The resulting test has six components. These are:

(1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person’s current condition constitutes a “significant aggravation” of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

In attempting to carry their burdens, petitioners must rely upon “medical records or medical opinion.” 42 U.S.C. § 300aa–13(a)(1).<sup>4</sup>

#### **IV. Summary of Ms. Duncan’s Evidence**

Although Ms. Duncan might rely upon a “medical record,” she has not identified any treating doctor’s reports that support her claim.<sup>5</sup> See Pet’r’s Resp.; see also Vaccine Rule 8(f)(1). It appears that no treating doctor offered the opinion that an HPV vaccination affected Ms. Duncan’s PANDAS. See Resp’t’s Rep. at 7. Thus, Ms. Duncan is necessarily relying upon the “medical opinions.”

Ms. Duncan’s response to the order to show cause relies upon opinions presented by Dr. Joseph and Mr. Lyons-Weiler. These are considered in chronological order, beginning with the earliest.

##### **A. Dr. Joseph’s Background and his April 21, 2017 Letter**

Dr. Joseph graduated from Creighton University School of Medicine in 1993. He is board-certified in pediatrics and, at the time his curriculum vitae was submitted, was teaching at the Ohio State University School of Medicine. He has written at least 15 articles, mostly on the topic of chronic pain in pediatrics. Exhibit 58 (curriculum vitae); exhibit 58 (Dr. Joseph’s report).

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<sup>4</sup> With respect to the third Loving element, “whether the person’s current condition constitutes a “significant aggravation” of the person’s condition prior to vaccination,” the burden of proof seems to be in flux. Periodically, based upon Locane v. Sec’y of Health & Human Servs., 99 Fed. Cl. 715, 731-32 (2011), aff’d, 685 F.3d 1375, 1381-82 (Fed. Cir. 2012), the undersigned has directed Ms. Duncan and her experts to explain how her course of PANDAS was worse than the expected course of PANDAS. E.g., Order, issued Feb. 22, 2019; Feb. 24, 2020 (order to show cause).

However, during this litigation, the Federal Circuit stated that the burden of proof regarding any similarities between the person’s actual condition and the person’s hypothetical condition based on the natural course of the condition falls to the Secretary. Sharpe v. Sec’y of Health & Human Servs., 964 F.3d 1072 (Fed. Cir. 2020), pet. for rehear’g filed Sept. 8, 2020. The August 31, 2020 order informed the parties of the Sharpe opinion.

<sup>5</sup> Although Dr. Joseph, a treating doctor, offered a supportive opinion after the litigation commenced, Dr. Joseph did not offer an opinion that an HPV vaccination affected Ms. Duncan’s PANDAS while he was treating Ms. Duncan before litigation commenced. See exhibit 28.

Dr. Joseph presented his opinion through two documents.<sup>6</sup> First, Dr. Joseph wrote a one-page letter, dated April 21, 2017. Exhibit 31. In this short statement, Dr. Joseph states that before the HPV vaccination, Ms. Duncan had “the sensation of needlelike pain in her extremities and moderate fatigue.” Id. Ms. Duncan was “diagnosed with complex regional pain syndrome as well as PANDAS.” Id. “Although she was struggling[,] she was still able to continue in school as well as extracurricular activities.”

Dr. Joseph continues Ms. Duncan’s history. He stated that “in late 2013,” Ms. Duncan received the second dose of the HPV vaccine. Then, “[i]n early 2014 her symptoms escalated severely. She became unable to attend school, dance or participate in acting, all activities that she enjoyed previously.” Id. Ms. Duncan “suffered from burning left leg pain, muscle spasms, temperature instability, joint swelling[,] skin sensitivity, shock like pain throughout her body, sensation of itching, severe fatigue, migraines, anxiety and depression.” Id.

Dr. Joseph concluded that “It is my medical opinion that the [HPV vaccination] greatly exacerbated the symptoms and disability the young woman who inherited the propensity for and was already suffering from significant nervous system deregulation.” Id. In this letter, Dr. Joseph does not explain how the HPV vaccination aggravated Ms. Duncan’s pre-existing conditions.

As noted in the procedural history, Ms. Duncan was advised to provide more information. Order, issued June 6, 2017. In response, Ms. Duncan filed the first report from Mr. Lyons-Weiler.

## **B. Mr. Lyons-Weiler’s Background and November 26, 2018 Report**

Mr. Lyons-Weiler has a Master of Science in zoology from the Ohio State University and a Ph.D. in ecology, evolution, and conservation biology from the University of Nevada, Reno. Since 2015, he has been the chief operating officer, director, and senior research scientist at The Institute for Pure and Applied Knowledge. From 2006-14, he worked as a director or senior research scientist at Bioinformatics Analysis Core affiliated with the University of Pittsburgh. In this position, he developed software for whole genome association studies. He has written at least 40 articles. Exhibit 56 (curriculum vitae). Mr. Lyons-Weiler describes himself as “focusing on the identification of epitopes in pathogens that

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<sup>6</sup> While Mr. Blumenstiel stated that another report from Dr. Joseph might be forthcoming (Pet’r’s Status Rep., filed July 31, 2020), Mr. Blumenstiel has neither submitted another report nor sought an enlargement of time to file another report.

may induce autoimmunity in humans.” Exhibit 39 (report, dated Nov. 27, 2018) at 1.

After a discussion of his qualifications, Mr. Lyons-Weiler identifies the material he viewed. His list begins with Ms. Duncan’s vaccination record as well as four affidavits (exhibits 1-2, 32-33). Mr. Lyons-Weiler also states that he reviewed: “portions of Rochester Immediate Care medical records (exhibit 27),” “portions of Webster Medical Group P.C. medical records (exhibit 38),” “portions of University of Rochester Medical Center medical records (exhibit 26),” and the “April 23, 2014 medical record of Dr. Susan Schulman, MD FAAP (exhibit 7).”

To the credit of Mr. Lyons-Weiler, he cited these sources when he presented the chronology of events in Ms. Duncan’s life. The primary sources on which Mr. Lyons-Weiler relied were the affidavit of Ms. Duncan (exhibit 1) and the affidavit of Ms. Duncan’s mother, Khrystine Duncan (exhibit 2). See exhibit 39 at 3-4.

Mr. Lyons-Weiler offered a medical theory by which an HPV vaccination can significantly aggravate PANDAS: “molecular mimicry and self-antigen attack by the adaptive immune system.” Exhibit 39 at 4. He links abnormally folded proteins to endoplasmic reticulum stress, although this link is not articulated clearly. He asserts that “ER stress itself is ubiquitously accepted as a fundamental core process factor in many types of diseases and disorders, especially autoimmunity.” Id.<sup>7</sup> Mr. Lyons-Weiler hypothesizes “If the Petitioner has self proteins that are similar to any of the various Strep A proteins, or self proteins that are similar to Human Papillomavirus proteins, or both, the theory of autoimmunity via molecular mimicry would readily apply.” Id. at 5. He identifies 17 articles in support but did not identify which articles correspond to which assertions.

On the question of timing, Mr. Lyons-Weiler states “it is acceptable for HPV to be considered the cause of a significant aggravation of PANDAS if the symptoms initiate anywhere from 0 to 365 days following the administration of a single dose of the vaccine. If boosters are given, the timeframe is extended beyond that to an additional 0 to 365 days.” Id. at 6. He maintains: “Based on the information provided to me, [Ms. Duncan] first began to experience a consequence

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<sup>7</sup> Mr. Lyons-Weiler references an 11-page appendix to his report that Mr. Lyons-Weiler describes as being accepted “this month” for publication in a peer-reviewed journal. However, Mr. Lyons-Weiler did not provide a citation to the journal that published his paper when he wrote a report in July 2020 and Ms. Duncan did not submit the published article as an exhibit. Searching the internet did not produce any articles by Mr. Lyons-Weiler about PANDAS. Nevertheless, the undersigned has reviewed the appendix to Mr. Lyons-Weiler’s first report.

of the HPV vaccination ‘shortly,’ which I take to mean within a month following the vaccination.” Id.

Mr. Lyons-Weiler ruled out other potential causes. He, therefore, concluded that the HPV vaccination “cause[d] a significant aggravation of the pre-existing PANDAS symptoms [Ms. Duncan] had at the time of vaccination.” Id. at 7.

### **C. Dr. Joseph’s November 25, 2019 Report**

Approximately two years after his first letter, Dr. Joseph addressed questions presented in the August 8, 2017 Instructions. Exhibit 58 (report, dated Nov. 25, 2019). Dr. Joseph disclosed that he reviewed four affidavits (exhibits 1-2, 32-33), and Ms. Duncan’s vaccination record (exhibit 27), medical records from October 4, 2012; January 16, 2014; February 4, 2014; and April 23, 2014 (all contained in either exhibit 26B or exhibit 27), and his own records of Ms. Duncan (exhibit 28). Dr. Joseph also disclosed that he had reviewed his earlier April 21, 2017 letter as well as the report from Mr. Lyons-Weiler. The history of events Mr. Lyons-Weiler presented in his November 26, 2018 report may have served as the foundation for recitation of events in Dr. Joseph’s November 25, 2019 report as they are similar.

Dr. Joseph also appears to have relied upon the earlier work of Mr. Lyons-Weiler to explain how an HPV vaccination can significantly aggravate PANDAS. Dr. Joseph proposed two medical mechanisms:

- 1) The inducement of further autoimmunity via molecular mimicry between pathogen proteins in the vaccine and the proteins Jacqueline had in her body at the time of vaccination, and
- 2) Inducement of a sustained adaptive immunological response in the presence of the relapse of strangely folded proteins due to the direct effects of aluminum and thimerosal on endoplasmic reticulum stress (RE stress).

Exhibit 58 at 3. Dr. Joseph did not cite any articles discussing those theories, although Dr. Joseph, as mentioned, cited the report from Mr. Lyons-Weiler.

With respect to timing, Dr. Joseph proposed that an adverse reaction to the HPV vaccination “can occur at any time between 0 to 365 days following the administration of the vaccination.” Id. at 4. Dr. Joseph opined that Ms. Duncan “began to experience her symptoms within a few days of the October 28, 2013 [HPV] vaccination.” Id. at 3. Dr. Joseph did not identify which specific symptoms

she began to experience or which ones worsened, and he did not identify any evidence on which this portion of his opinion was based.

Dr. Joseph again concluded that the HPV vaccination significantly aggravated Ms. Duncan's pre-existing health problems.

#### **D. Mr. Lyons-Weiler's July 20, 2020 Report**

In response to the order to show cause, Mr. Blumenstiel obtained another report from Mr. Lyons-Weiler, which is one page. Exhibit 66. Mr. Lyons-Weiler wrote one paragraph about molecular mimicry and one paragraph about the expected course of PANDAS. He did not cite any additional articles.

### **V. Evaluation of Ms. Duncan's Evidence**

Ms. Duncan's evidence, even without any contrary evidence from an expert the Secretary retains, does not preponderate in favor of finding that the HPV vaccination significantly aggravated her PANDAS. Two interrelated reasons support this finding: the qualifications of the people who have rendered opinions for Ms. Duncan and the opinions that they have presented.

#### **A. Qualifications**

Special masters may consider the relative expertise of testifying experts when weighing the value of their opinion. See Depena v. Sec'y of Health & Human Servs., No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 Fed. App'x 938 (Fed. Cir. 2018); Copenhaver v. Sec'y of Health & Human Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016).

##### **1. Mr. Lyons-Weiler**

Ms. Duncan has not established that Mr. Lyons-Weiler possesses adequate background to present the opinions he has offered. To take one example, in his July 20, 2020 report, Mr. Lyons-Weiler opined about the expected course of PANDAS. Exhibit 66. However, Mr. Lyons-Weiler does not possess a medical license. He has not indicated that he treated any patients with PANDAS. His curriculum vitae does not indicate that he studied or researched PANDAS. Mr. Lyons-Weiler's willingness to opine upon a topic on which he seems to possess no qualifications renders suspect his credibility.

Special masters have not endorsed opinions from Mr. Lyons-Weiler. In deciding a case in which petitioners alleged that vaccines caused their child's autism, a special master found "fundamentally, Dr. Lyons-Weiler appears to be wholly unqualified to opine on the question of vaccine causation. His academic training centered on zoology and ecology, not medicine or immunology, and he does not appear to have performed research or published peer-reviewed work on any subject relevant to the present matter." A.S. v. Sec'y of Health & Human Servs., No. 16-551V, 2019 WL 5098964, at \*11 (Fed. Cl. Spec. Mstr. Aug. 27, 2019). Later, this same special master found that despite the presence of reports from Mr. Lyons-Weiler, the case lacked a reasonable basis. A.S. v. Sec'y of Health & Human Servs., No. 16-551V, 2020 WL 549443 (Fed. Cl. Spec. Mstr. Jan. 3, 2020). A different special master gave documents Mr. Lyons-Weiler submitted "little weight," in part because petitioner failed to submit information about Mr. Lyons-Weiler's background. Kamppi v. Sec'y of Health & Human Servs., No. 15-1013V, 2019 WL 5483161, at \*11 (Fed. Cl. Spec. Mstr. July 24, 2019). On the other hand, the Federal Circuit suggested that Mr. Lyons-Weiler's work, when combined with reports from other people, would allow a petitioner to survive a motion for summary judgment. Moczek v. Sec'y of Health & Human Servs., 776 F. App'x 671, 675 (Fed. Cir. 2019).

The undersigned attempted to alert Mr. Blumenstiel and Ms. Duncan to shortcomings in Mr. Lyons-Weiler's background by presenting an article in which the author challenged Mr. Lyons-Weiler's methodology. Order issued Feb. 22, 2019, court exhibit 1001 (James Lyon-Weiler and IPAK are running a dubious "vaxxed versus unvaxxed" study, Respectful Insolence, <https://respectfulinsolence.com/2019/01/25/ipak-running-dubious-study/>); see also Order to Show Cause at 2, citing A.S. This warning appears not to have been heeded as neither Mr. Blumenstiel nor Mr. Lyons-Weiler responded to defend his scientific credentials.

Another problem with Mr. Lyons-Weiler's methodology as an expert witness is his selective reliance upon questionable source material. As noted earlier, Mr. Lyons-Weiler relied upon only a portion of the records and accepted assertions made in the affidavits from Ms. Duncan and her mother. However, the accuracy of these recollections seems questionable. Both state that Ms. Duncan was a "straight A" student. Exhibit 1 (Ms. Duncan's affidavit) ¶ 4, exhibit 2 (Khrystine Duncan's affidavit) ¶ 4. Yet, Ms. Duncan's high school records show that in her first year, which was before she received the allegedly causal HPV vaccination, she received only two credits because she did not pass many courses. Exhibit 29 at 1. In Ms. Duncan's junior year during which she received the

allegedly causal HPV vaccination, she received 4.5 credits and had an unweighted GPA of 76. Id.

Whether Mr. Lyons-Weiler actually knew about this material is unclear. However, Mr. Lyons-Weiler should have known that he had incomplete information. To start, a 14-year-old woman would normally be attending school and receiving reports cards. Thus, Mr. Lyons-Weiler could have asked Mr. Blumenstiel for them. In addition, the undersigned encouraged the individuals submitting reports to review Ms. Duncan's school records. Instructions, issued Aug. 8, 2017, at 4 n.2. Moreover, the face of Mr. Lyons-Weiler's report shows that Mr. Lyons-Weiler received only a portion of the exhibits because he did not review, for example, exhibits 3-25. By not considering all the available information about Ms. Duncan, Mr. Lyons-Weiler has presented a deficient report.

Under these circumstances, the undersigned cannot give the opinions of Mr. Lyons-Weiler more than minimal weight.

## 2. Dr. Joseph

The same concern about the methodology as an expert that reduces the value of Mr. Lyons-Weiler's work impairs the value of Dr. Joseph's report. Dr. Joseph, too, reviewed only a limited amount of the record. He does not indicate that he considered exhibits 3-25. See exhibit 58; see also Order to Show Cause at 3 (noting that Dr. Joseph did not consider all medical records). Further, contrary to the Instructions, Dr. Joseph did not identify the basis for his assertions about Ms. Duncan's history. This omission, too, reduces the weight to be given to Dr. Joseph's work because Ms. Duncan, as proponent of Dr. Joseph's opinion, bears the burden of establishing the reliability of that opinion including the foundation for the opinion.

Dr. Joseph's experience in treating Ms. Duncan does not cure these problems. While a treating doctor's opinion can be valuable, Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006), it is not sacrosanct. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 745 n.67 (2009). Here, Dr. Joseph only began treating Ms. Duncan in March 2016. Exhibit 28 at 4, 10. After Ms. Duncan treated with Dr. Joseph for six months, Dr. Joseph first mentioned the October 28, 2013 HPV vaccination in his records when Ms. Duncan and her mother reported that "they have had a revelation that [Ms. Duncan's] symptoms became significantly worse after her [HPV] vaccine." Exhibit 28 at 54. In the records filed from Dr. Joseph (only through December 2016), he does not comment on the suggestion that the HPV vaccination affected Ms. Duncan.

The degree to which Dr. Joseph has experience in treating PANDAS is not clear. Although directed to disclose his experience in treating patients with PANDAS (Instructions, issued Aug. 8, 2017, ¶ 1.c), Dr. Joseph did not answer this question.

If Dr. Joseph had disclosed any practical experience with PANDAS, this information might have enhanced his standing. While Dr. Joseph appears entirely qualified to discuss chronic pain in a pediatric population, Dr. Joseph does not connect his experience in treating chronic pain to an ability to opine on the etiology of PANDAS. Typical cases of PANDAS appear not to present with chronic pain. See exhibit 60 (article from website of National Institute of Health about PANDAS).

Most critically, Dr. Joseph appears not to have any specialized experienced in immunology and appears not to have performed any research with respect to molecular mimicry or endoplasmic reticulum stress. See exhibit 58(curriculum vitae). Given the brevity of his report about these theories, it appears that Dr. Joseph's opinion derives from the work of Mr. Lyons-Weiler. However, for the reasons discussed above, the work of Mr. Lyons-Weiler merits little weight. Ms. Duncan does not strengthen Mr. Lyons-Weiler's work simply by passing it through another expert. See Ramirez v. Dep't of Homeland Security, 2020 WL 5523207 \_\_\_ F.3d \_\_\_ (Fed. Cir. 2020).

Accordingly, based strictly on qualifications, Ms. Duncan's experts do not collectively present a minimally credible case that the October 2013 HPV vaccination affected her PANDAS. Their lack of qualifications in the relevant disciplines, in turn, affected the persuasiveness of the opinions that they offered.

## **B. Substance**

The dismissal of Ms. Duncan's petition does not rest solely upon the weakness of the credentials of her experts. Even if those deficiencies could be set aside, the experts have expressed opinions that are not persuasive. The lack of persuasiveness is particularly evident with respect to Loving prong 4 (Althen prong 1) and Loving prong 6 (Althen prong 3).<sup>8</sup>

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<sup>8</sup> Loving prong 3, a comparison between the vaccinee's condition before and after the vaccination, does not contribute to dismissal.

1. Loving prong 4 / Althen prong 1 – a medical theory

In briefing, Ms. Duncan relies upon molecular mimicry as articulated by Mr. Lyons-Weiler and Dr. Joseph. Pet'r's Resp. to Order to Show Cause at 6. In this context, Ms. Duncan cited a single article, exhibit 60.<sup>9</sup>

Exhibit 60 is an article from the website of the National Institute of Health. Here, the (unnamed) author recognizes that an infection with strep bacteria leads to pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) via molecular mimicry. Exhibit 60 at 2. The article does not discuss or even mention the HPV vaccine.

But, neither Mr. Lyons-Weiler, Dr. Joseph, nor Ms. Duncan explain why the finding for strep bacteria should be extended to the HPV vaccine. No one has asserted that the molecular structure of strep bacteria resembles in any way the molecular structure of the HPV vaccine. If there were some asserted similarity between strep bacteria and the HPV vaccine, then there might be some reliable basis for extrapolating from strep bacteria to the HPV vaccine. Without this showing, there is a gap in the opinions from Mr. Lyons-Weiler and Dr. Joseph.

A bare assertion of molecular mimicry does not necessarily meet a petitioner's burden of proof with respect to the requirement to produce a reliable medical theory. Tullio v. Sec'y of Health & Human Servs., No. 15-51V, 2019 WL 7580149, at \*12-13 (Fed. Cl. Spec. Mstr. Dec. 19, 2019) (citing cases), mot. for review denied, 2020 WL 4593161 (Fed. Cl. June 18, 2020). As noted above, the molecular mimicry theory must be specific to the case at hand providing some reason the molecular structure of the vaccine is mimicking a molecular structure of the body resulting in the immune system attacking the body. Ms. Duncan has not provided sufficient support to establish a persuasive theory connecting the HPV vaccine to PANDAS.

2. Loving prong 6 / Althen prong 3 – timing

The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Human Servs.,

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<sup>9</sup> Ms. Duncan did not rely upon the theory of endoplasmic reticulum stress. See Pet'r's Resp. to Order to Show Cause. Thus, the undersigned considers this theory waived. See Vaccine Rule 8(f)(1). Even if the theory were not waived, the theory is so thinly developed that Ms. Duncan has not established its persuasiveness.

101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

Here, both Mr. Lyons-Weiler and Dr. Joseph opine that the time from which an inference of causation is appropriate ranges from 0 to 365 days. Exhibit 39 at 6, exhibit 58 at 4. Ms. Duncan proposes a narrower span: 1 to 20 days (i.e., by November 17, 2013). Pet'r's Resp. to Order to Show Cause at 8, citing exhibit 67 (Palmieri et al, Severe somatoform and dysautonomic syndromes after HPV vaccination: case series and review of literature, 65 Immunol. Res. 106 (2017)). Simply for sake of argument, this shorter range can be accepted as reasonable.

However, Ms. Duncan has not established that her pre-existing PANDAS worsened within 20 days of the October 28, 2013 vaccination. According to the Secretary's report, after the vaccination, Ms. Duncan first sought medical treatment on January 14, 2014 at Rochester General Hospital. There, she reported that she "had a virus, sinus infection, [and] ear ache last week." Exhibit 24 at 10. She also informed doctors that she had "bee stings all over [her] body," fatigue, chest pain, and anxiety. Id. Even Ms. Duncan's experts do not anchor a 20-day onset. Dr. Joseph stated that Ms. Duncan's symptoms "escalated severely" in "early 2014," exhibit 31, and Mr. Lyons-Weiler vaguely stated that Ms. Duncan began experiencing worsening symptoms "shortly" after the vaccination "based on the information provided to [him]." Exhibit 39 at 6.

The undersigned cites the Secretary's report because Ms. Duncan has not cited medical records in any pleading. See Pet.; Pet'r's Resp. to Order to Show Cause. (The undersigned's own review of the record similarly has not identified any records created around the time of the October 28, 2013 vaccination that suggests Ms. Duncan experienced any health problems then.) This omission weakens Ms. Duncan's case because "[m]edical records, in general, warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Instead of relying upon reports communicated to doctors created contemporaneously with the events happening, Ms. Duncan relies upon affidavits from her and her mother. Pet'r's Resp. to Order to Show Cause at 8, citing exhibits 1 and 2 for the proposition that Ms. Duncan's "symptoms began 'within a few days' of receiving the vaccination." These exhibits do support this proposition. See exhibit 1 ¶ 17; exhibit 2 ¶ 16.

However, Ms. Duncan has not established the accuracy of these recollections, which were memorialized in October 2016, approximately three years after the events allegedly happened. The adoption of Ms. Duncan's account

by her experts does not confer reliability automatically. Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

Moreover, Mr. Lyons-Weiler and Dr. Joseph do not explain what “symptoms” that Ms. Duncan allegedly suffered within a few days of the October 28, 2013 vaccination constituted a worsening of her PANDAS. PANDAS can present differently in different people. Thus, Ms. Duncan should have identified the specific ways in which her PANDAS became worse. See Instructions ¶ 6.a.iii. The omission of this information in the expert reports leaves another gap in Ms. Duncan’s case.

Finally, Ms. Duncan’s failure to present persuasive evidence that any symptoms of PANDAS worsened within an appropriate timeframe (Loving prong 6 / Althen prong 3) implicates her proof on the “logical sequence” element (Loving prong 5 / Althen prong 2). Because the timing of any worsening for Ms. Duncan’s PANDAS does not fit what is expected, her claim is no longer “logical.” See Caves v. Sec’y of Health & Human Servs., 100 Fed. Cl. 119, 145 (2011), aff’d without opinion, 463 F. App’x 932 (Fed. Cir. 2012). Thus, although Ms. Duncan’s lack of evidence regarding Loving prong 6 / Althen prong 3 is not the primary reason for dismissing her case, she has also not presented reliable evidence on this element as well.

## **VI. Conclusion**

Ms. Duncan has had multiple opportunities to ground her claim that an HPV vaccination significantly aggravated her PANDAS. However, she has produced only weak reports from people who are lacking in qualifications. She has not presented evidence that carries persuasiveness on elements for which she bears the burden of proof. Consequently, her case is dismissed.

The Clerk’s Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

**IT IS SO ORDERED.**

s/Christian J. Moran  
Christian J. Moran  
Special Master